



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/577,268	12/18/2006	Tove Ringerike	76222-PCT-US/GJG	2090
23432 7590 11/13/2009 COOPER & DUNHAM, LLP 30 Rockefeller Plaza 20th Floor NEW YORK, NY 10112			EXAMINER HIBBERT, CATHERINE S	
			ART UNIT 1636	PAPER NUMBER
			MAIL DATE 11/13/2009	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/577,268	Applicant(s) RINGERIKE ET AL.	
	Examiner CATHERINE HIBBERT	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 August 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9, 11-13, 15, 16 and 24 is/are pending in the application.
- 4a) Of the above claim(s) 24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 11-13, 15 and 16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 April 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/26/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This is the First Office Action on the Merits of US Application 10/577,268 filed 26 April 2006, which is a 371 National Stage entry of PCT/PL2004/000075, filed 26 September 2004, which claims foreign priority to PCT/PL2003/000098, filed 26 September 2003. Claims 1-9, 11-13 and 15-16 and 24 are pending. Claim 24 is withdrawn to non-elected subject matter. Claims 1-9, 11-13 and 15-16 are under examination in this action.

Election/Restrictions

Applicant's election of the invention of Group I (Claims 1-9, 11-13 and 15-16) and of the species:

- SEQ ID NO:10 (from among SEQ ID NO:s 1-35 (e.g. Claims 4 and 8),
- EL4 T-cells (e.g. one type cell line from Claim 15), and
- the cell line EL/p1-5' IL2-dEGFP/6 (e.g. one type of cell line from Claim 16),

in the reply filed on 29 July 2009 is acknowledged.

Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claim 24 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 29 July 2009.

Drawings

The drawings are objected to because the photos of Figure 22 are illegible and the text of Figures 23 and 24 is illegible. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-9, 11-13 and 15-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding Claims 2 and 6, a broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949).

In the present instance, claims 2 and 6 recite the broad recitation "a Green Fluorescent Protein (GFP), and the claims also recite "possibly selected from its variants: d1EGFP, d2EGFP, EGFP or EGFP-F" which is the narrower statement of the range/limitation.

Claim 12 recites the broad recitation "an immortal cell line", and the claim also recites "preferentially descendant from" which is the narrower statement of the range/limitation.

Art Unit: 1636

Regarding Claims 1, 3, 5 and 7, the claims are indefinite in reciting the term "originate from". It is not clear what is encompassed by the term "originate from" regarding a cytokine sequence to define the metes and bounds of the claim.

Claims 2, 4, 6, 8-9, 11-13 and 15-16 are indefinite insofar as they depend from Claims 1, 3, 5 and 7.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3, 5-7, 9, 11-13 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by Frazer et al (US PG PUB 2002/132290, 19 September 2002; whole document, of record).

Claims 1-3, 5-7, 9, 11-13 and 15 are rejected under 35 U.S.C. 102(e) as being anticipated by Glimcher et al (US Patent 7,393,944, filed 3 December 2001; whole document).

Claims 1 and 5 are drawn to an isolated nucleic acid molecule and expression vector containing the nucleic acid molecule, the nucleic acid molecule coding the expression box with the formula: S1-S2-S3 wherein: S1 is a promoter sequence, or it is absent, S2 is a known reporter gene sequence, S3 is a regulatory 3' UTR sequence, or it is absent, where the promoter sequence and the regulatory 3' UTR sequence

Art Unit: 1636

originate from a known cytokine gene, and are the controlling sequences of said cytokine.

Claims 2 and 6 specify within Claims 1 and 5, respectively, that the reporter gene is a gene coding a GFP.

Claims 3 and 7 specify within Claims 1 and 5, respectively, that the promoter sequence and regulatory 3' UTR sequence originate from a cytokine selected from among: IL-1 β , IL-2, TNF α , IL-4, IL10 or INF α .

Claim 9 is drawn to a single-celled host transformed or transfected with a DNA molecule according to claim 1.

Claim 11 specifies within Claim 9 that the host cell is selected from the group encompassing bacteria, yeast, mammalian cells, plant cells, insect cells, as well as eukaryotic cell lines.

Claim 12 is drawn to the single-celled host according to claim 11, characterized in that it is an immortal mammalian cell line, preferentially descendant from cells of the immune system.

Claim 13 is drawn to the single-celled host according to claim 11, characterized in that it is a cell line selected from among T cell leukemia cells, thymoma, mast cells, macrophage-monocytes, fibroblasts and keratinocytes.

Claim 15 is drawn to the single-celled host according to claim 11, characterized in that it is the cell line EL4 (T-cells).

Claim interpretation: Initially it is noted that the base Claim 1 reads on any isolated nucleic acid molecule coding a known reporter gene sequence and Claim 5

Art Unit: 1636

reads on any expression vector containing a nucleic acid molecule coding a known reporter gene sequence because both of the base Claims 1 and 5 encompass the embodiments of wherein the promoter sequence and the 3' UTR sequence are absent.

The reference of Frazer et al teaches expression vector constructs containing an isolated nucleic acid molecule coding the expression box with the formula: S_1 - S_2 - S_3 wherein S_1 is a promoter, S_2 is a GFP reporter gene, and S_3 is a regulatory 3'UTR sequence, where the promoter and 3'UTR sequences originate from a known cytokine gene and are the controlling sequences of the cytokine (e.g. paragraph 0003 and 0017) In addition, Frazer et al contemplate using EL4 T-cell host cells (paragraph 0139, line 3) which meets the limitations of Claims 1-3, 5-7, 9, 11-13 and 15.

The reference of Glimcher et al teaches nucleic acid expression vectors containing recombinant/isolated IL-2 promoter sequence and GFP reporter sequence and Glimcher et al explicitly recite using EL4 T-cell host cells for expression of the constructs (e.g. Column 52, Example 7, lines 54-56 and Column 52, Example 7, lines 37-40) which meets the limitations of Claims 1-3, 5-7, 9, 11-13 and 15.

State of the Art

The sequence consisting of SEQ ID NO:10 is free of the art.

Conclusion

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CATHERINE HIBBERT whose telephone number is (571)270-3053. The examiner can normally be reached on M-F 8AM-5PM, EST.

Art Unit: 1636

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Respectfully submitted,

Catherine Hibbert
Examiner AU1636

/ Christopher S. F. Low /
Supervisory Patent Examiner, Art Unit 1636